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Foley & Lardner
Washington Harbour
3000 K Street N W Suite 500
Washington, DC 20007-5109

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/583,738	Applicant(s) Ghanbari
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 19, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *23-33, 35-47, 49, and 50* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *23-33, 35-47, 49, and 50* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 34 and 48 have been canceled.

Claims 23-33, 35-47 and 49-50 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

2.Claims 23 and 37 rejected under 35 U.S.C. 112, second paragraph recite the phrase "the preparation consists essentially of two or more bacteriophage". This phrase defines the preparation to contain only TWO bacteriophage particles. How can only two bacteriophage particles be effective in treating infection of a mammal infected with a plurality of pathogenic bacteria? Does this phrase intend to define the preparation as containing two different types of bacteriophage? Clarification is requested.

3. Claims 23 and 37 rejected under 35 U.S.C. 112, second paragraph, as the claims no longer recite the phrase "substantially kill" in the preamble.

4.Claims 34 and 48 rejected under 35 U.S.C. 112, second paragraph, because the claims have been canceled.

5. Claims 23-24, 33-34, 37-38, 47-48 rejected under 35 U.S.C. 102(b) as being anticipated by Soothill (1992, Journal of Medical Microbiology), in light of the claims having been amended to recite new claim limitations.

6. Claims 23, 35, 37 49 rejected under 35 U.S.C. 102(b) as being anticipated by Sakandelidze (1991, abstract), in light of the claims having been amended to recite new claim limitations.

7. Claims 23-24, 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogovazova et al (1991, abstract), in light of the fact that the polyvalent bacteriophage preparation directed against Klebsiella is not so defined to meet the amended claim limitations.

Rejections Maintained

8. Claim 23 rejected under 35 U.S.C. 112, second paragraph recites the phrases because the claims though amended are still unclear as to the specificity of the "a bacterial organism" (preamble) and "the bacteriophage preparation consisting of two or more bacteriophage" relative to the claimed method of treating bacterial infection, for reasons of record in paper number 7, paragraph 3, subparagraph 1.

9. Claims 33 and 47 rejected under 35 U.S.C. 112, second paragraph for the recitation of the phrase "wherein the preparation is resistant to one or more properties selected from the group consisting of" because what in the preparation provides for the resistance characteristics has not been distinctly claimed; no carrier or bacteriophage that has or provides for one or all of the recited resistence characteristics have been distinctly claimed. The rejection is maintained for reasons of record in paper number 7, paragrpah 3, subparagraph 4.

10. Claims 23-25, 29-30,33-39,43-44,47-50 rejected under 35 U.S.C. 102(e) as being anticipated by Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994), for reasons of record in paper number 7, paragraph 5.

11. Claims 23-24, 33-34, 37-38, 47-48 rejected under 35 U.S.C. 102(b) as being anticipated by Norris (US Pat. 4,957,686)for reasons of record in paper number 7, paragraph 6.

12. Claims 26 and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Denney (US Pat. 3,793,151), for reasons of record in paper number 7, paragraph 11.

13. Claims 27 and 41 rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of He et al (1992), for reasons of record in paper number 7, paragraph 12.

14. Claims 28 and 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-

39,43-44,47-50 above, in view of Sekaninova et al (1995),for reasons of record in paper number 7, paragraph 13.

15. Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Bar-Shalom et al (US Pat. 5,213,808), for reasons of record in paper number 7, paragraph 14.

16. Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Tomalia et al (US Pat. 5,714,166), for reasons of record in paper number 7, paragraph 15.

Response To Arguments

17. The rejection of claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is asserted to have been obviated by amending the claim to recite the phrase "bacteriophage strains".

18. It is the position of the examiner, while the claim amendment partially obviates the rejection under 35 U.S.C. 112, second paragraph, claim 23 is still unclear with respect to how many

bacterial infections are being treated because the preamble recites the phase "bacterial infection" in the singular tense and the preparation contains a plurality of bacteriophages. Is the method for treatment of one or multiple infecting bacterial infections; Are the bacteriophage that kill the bacterial organism of the preamble effective against the same or different bacteria from which the bacteriophage are screened? How do the two or more bacteriophage strains relate to the bacterial organism recited in the preamble of the claim? There is still a lack of agreement between the strains of bacteriophage and the preamble of the claim that is directed to treating any type of bacterial infection. A point of clarification, the examiner is not requesting the preamble to be amended to recite any specific bacterial genera, but would like the administered bacteriophage to be defined to be specific for the bacterial infection treated. The rejection is partially obviated and partially maintained, in light of claim 23 only being amended to address a portion of the issues raised upon 112, second paragraph, for reasons of record in paper number 7, paragraph 3, first sub-paragraph.

19. The rejection of claims 33 and 47 under 35 U.S.C. 112, second paragraph is asserted to be clear in light of the specification, specifically pages 5, 7, 11,14, and 21. Applicant admits at page 5, paragraph 4, that "claims 22 and 47 are not clear."

20. It is the position of the examiner that the claims are read in light of the specification but are given the broadest reasonable interpretation of the claimed subject matter. Claims 33 and 47 set

forth a characteristic of the preparation without defining what provides the characteristic to the preparation. The preparation contains two components, the carrier and the bacteriophage.

Resistance to high temperatures, to drying, lytic agents, to mutator hosts, to heat shock or to ionic variation are not natural characteristics of the components that make up bacteriophages (proteins and nucleic acid material).

Does the carrier provide the recited functionalities to the preparation or do the bacteriophage have the recited functionalities? No bacteriophage preparations have been so claimed as to have been selected to have all of these characteristics naturally, nor have the resistance characteristics been so claimed due to carrier added to the preparation. The rejection is maintained for reasons of record in paper number 7, paragraph 3, page 4, paragraph 2.

21. The rejection of claims 23-25, 29-30,33-39,43-44,47-50 under 35 U.S.C. 102(e) as being anticipated by Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) is asserted to not teach bacteriophage having a "broad host range".

22. It is the position of the examiner that the claims recite the phrase "wide host range" and not the phrase "broad host range" as argued.

The recited "wide host range" is defined in the claims to be a bacteriophage preparation that "consists essentially of two or more bacteriophage strains, wherein each strain is selected against **one**" genus of recited bacteria. The preparation is characterized as having a wide host range because it contains two or more bacteriophage strains. The strains are not required in

themselves to be tested against more than one of the recited bacteria. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

23. Merrill et al is asserted to utilize bacteriophage that "are specific for each of the bacterial strains of interest" (col. 6, lines 63-67).

24. It is the position of the examiner that any bacteriophage used in therapy must be specific for the bacterial strains of interest in order for the bacteriophage to be able to infect and ultimately kill the bacterial host. A bacteriophage that is not specific for a strain of bacteria would not be effective in killing the bacteria, because the bacteria would be resistant to bacteriophage infection due to the lack of a specific bacteriophage receptor. The claimed invention requires the preparation to contain host-specific bacteriophage, as would the bacteriophage preparation of Merrill.

Merrill et al utilize bacteriophages that are effective in killing mycobacteria, staphylococci, vibrio, enterobacter, enterococcus, escherichia, haemophilus, neisseria, pseudomonas, shigella, serratia, salmonella, streptococcus, klebsiella and yersina (see claims 1 and 9). In example 6, Merrill et al utilized lambda coliphages (see col. 14, line 48-49) which would specifically interact with multiple strains of Escherichia coli based upon the lambda receptor being present in E.coli. The bacteriophages of Merrill et al are specific for a genus of bacteria which would include a plurality of species and strains (see claim 13, Merrill et al, col. 16, lines 34-39).

In addition, Merrill et al (see col. 1, lines 63-66) teach through citing Zhurnal mikrobiologii (April 1991, reference previously applied to the claims) and Zhurnal Mikrobiologii (March 1992) the utilization of a polyvalent bacteriophage preparation that contains bacteriophages for multiple species of Klebsiella, specifically K. rhinoscleromatis scleromatis, K. pneumoniae sensu lato and K.ozaenae. The guidance and teaching of these references define a wide host range, nontoxic, purified virulent bacteriophage preparation that was shown to be effective against infection (Zhurnal Mikrobiologii (March 1992) abstract provided with this action).

25. Applicant asserts the instant invention utilizes bacteriophages with a "broad host range" and Merrill et al require a full array of bacteriophage for treatment, while Applicant's claimed bacteriophage enable treatment with a single bacteriophage preparation.

26. It is the position of the examiner that the claims do not recite the phrase "broad host range" but "wide host range", wherein the "wide host range" preparation of bacteriophage is defined to contain two bacteriophage strains and each strain must be selected against one bacterial type recited in the claims. The bacterial type that each strain of bacteriophage is not required to differ one from the other, but must only be considered to be a separate strain of bacteriophage. Merrill et al, thru administering a full array of bacteriophages, accomplishes like that of Applicant's claims, the administration of a single bacteriophage preparation containing a plurality of strains of bacteriophage that enables treatment.

The examiner has established a prima facie case of anticipation, for reasons of record in paper number 7, paragraph 5.

27. The rejection of claims 23-24, 33-34, 37-38, 47-48 under 35 U.S.C. 102(b) as being anticipated by Norris (US Pat. 4,957,686) is asserted to not teach or disclose a "broad host range" bacteriophage.

28. It is the position of the examiner that the claimed invention does not recite the phrase "broad host range" bacteriophage, but recites "wide host range" which is defined in the claims to be a bacteriophage preparation that "consists essentially of two or more bacteriophage strains, wherein each strain is selected against one" of the recited bacteria. The bacteriophage preparation of Norris comprises two or more strains of bacteriophage (mixtures) which are virulent (parasitic to bacteria) and selected against S.sanguis (Norris, claim 3), and virulent and selected against bacteria normally present in the mouth, specifically defined to include bacteriophages specific for S.aureus(Norris, col. 3, line 19), S.mutans and strains of lactobacillus (see col. 1, line 25 and col. 3, line 2).

The preparation is characterized as having a wide host range because it contains two or more bacteriophage strains that would react and selected against different strains of bacterial organisms. The bacteriophage strains are not required in themselves to be tested against more than one of the recited bacteria, but the composition must comprise at least two bacteriophage strains, each of which were selected against a different bacterial organism, which would include

bacteriophages that are selected against different strains of the same genus and species thus defining a preparation with a specific wide host range.

No specific broad host range bacteriophages are recited in the claims, and only wide host range bacteriophage preparations that comprise two or more strains of bacteriophage are required to be in the preparation. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

29. The rejection of claims 26 and 40 under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Denney (US Pat. 3,793,151);

30. The rejection of Claims 27 and 41 under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of He et al (1992);

31. The rejection of claims 28 and 42 under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Sekaninova et al (1995) ;

32. The rejection of claims 31 and 45 under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Bar-Shalom et al (US Pat. 5,213,808) ; and

33. The rejection of claims 31 and 45 under 35 U.S.C. 103(a) as being unpatentable over Merrill et al (US Pat 5,688,501; effective filing date of April 5, 1994) as applied to claims 23-25, 29-30,33-39,43-44,47-50 above, in view of Tomalia et al (US Pat. 5,714,166) ;

are asserted by Applicant to not have established a prima facie case of obviousness for the claimed invention because Merrill et al do not teach a preparation that contains two or more bacteriophage strains as required by the claims.

34. It is the position of the examiner that Merrill et al teach the utilization of a "full array (see col. 7, line 1)" of bacteriophages in the treatment of bacterial infections (see col. 8, line 66), and is not limited to a specific bacteriophage or a specific bacteria, but utilizes bacteriophages that can be used to treat any and all infections (see col. 7, lines 22-26), as well as claim the utilization of bacteriophages that are specific for a genus of bacteria which would include at least two species of bacteria from that genus (see Merrill et al, claim 13).

Merrill et al also teach through citing prior art references in Zhurnal mikrobiologii (April 1991, reference abstract of record and March 1992), preparations of polyvalent bacteriophage (see Merrill et al, col. 1, lines 64-66). Zhurnal Mikrobiologii (March 1992) teach a bacteriophage preparation that contains bacteriophages for multiple strains/species of Klebsiella, specifically K.

rhinoscleromatis scleromatis, K. pneumoniae snsu lato and K.ozaenae (abstract provided herewith), wherein the preparation was safe, virulent and effective.

Clearly the bacteriophage preparation of Merrill et al is taught to contain a full array(col. 7, line 1) of bacteriophages (see col. 7, lines 24-25) for the treatment of bacterial infections (see col. 7, line 25) and would therefore comprise two or more strains of bacteriophage.

35. Merrill et al is asserted to not teach an in vitro assay where at least about 50% of the bacteria are killed.

36. It is the position of the examiner that the claimed method recites a single methods step of "administering" a composition and does not require the method to carry out an in-vitro assay, but must administer a composition that contains a bacteriophage preparation that has the capability to function in an in vitro assay to kill 50% of the bacteria in that assay.

The composition that is administered comprises a preparation. The preparation is defined through the recitation of a "wherein" clause, and defined to comprise a pharmaceutical carrier (section (b)) and a "purified, host specific, non-toxic, wide host-range, and virulent bacteriophage preparation" (section (a)).

The preparation is characterized to have specific components and capabilities. The capabilities are defined through narrative that define the capability to kill 50% of a bacterial population in an in-vitro assay.

Bacteriophage that are capable to providing protection in vivo through killing an LD_{50} dosage of bacteria (the bacteriophages of Merrill et al, Example 6, col. 14 to col. 15; and col. 11, lines 64-67) , would also have the capability of functioning to kill 50% of the same bacteria in an in-vitro assay.

Merrill et al teach and provide motivation for utilizing bacteriophage preparations that are effective to kill a plurality of bacterial species and strains of a specific genus of bacteria (see claim 13), as well as teach the utilization of a full array of bacteriophage preparations for the purpose of treating bacterial infections for which the bacteriophages(col. 7, lines 17-26) are effective in killing (col. 4, lines 40-44; the bacteria reduced to a number that enables the animal's defense system to completely eliminate the bacteria).

37. Denny is asserted to not remedy the deficiencies of Merrill et al.

38. It is the position of the examiner that the Merrill et al reference is not deficient as asserted, and Denny was cited to show a S.pyogenes specific phage (see Denny: col. 2, lines 56-66). The rejection of Merrill et al in view of Denny is maintained for reasons of record in paper number 7, paragraph 11.

39. He et al is asserted to not remedy the deficiencies of Merrill et al.

40. It is the position of the examiner that the Merrill et al reference is not deficient as asserted (see discussion above), and He et al was cited to show a Citrobacter freundii specific phage in an

analogous art for the purpose of showing a phage capable of infecting and lysing Citrobacter freundii (abstract, title). The rejection of Merrill et al in view of He et al is maintained for reasons of record in paper number 7, paragraph 12.

41. Sekaninova et al is asserted not to remedy the deficiencies of Merrill et al.

42. It is the position of the examiner that the Merrill et al reference is not deficient as asserted (see discussion above), and Sekaninova et al was cited to show a Klebsiella oxytoca specific phage in an analogous art for the purpose of showing a phage capable of infecting and lysing Klebsiella oxytoca (abstract). The rejection of Merrill et al in view of Sekaninova et al is maintained for reasons of record in paper number 7, paragraph 13.

43. Bar-Shalom et al is asserted not to remedy the deficiencies of Merrill et al.

44. It is the position of the examiner that the Merrill et al reference is not deficient as asserted (see discussion above), and Bar-Shalom et al (abstract, col. 9, lines 41-57; col. 9, lines 65-67 and col. 10, lines 1-3)). was cited to show liposomes in an analogous art for the purpose of showing means for delivering an active agent to a mammal, wherein an active agent is a bacteriophage. The rejection of Merrill et al in view of Bar-Shalom et al is maintained for reasons of record in paper number 7, paragraph 14.

45. Tomalia et al is asserted not to remedy the deficiencies of Merrill et al.

46. It is the position of the examiner that the Merrill et al reference is not deficient as asserted (see discussion above), and Tomalia et al was cited to show dentrimers provide a carrier means for the delivery of high concentrations of a phage material (col. 1, lines 39-43; col. 47, lines 1-3). The rejection of Merrill et al in view of Tomalia et al is maintained for reasons of record in paper number 7, paragraph 15.

Conclusion

47. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

48. DeVries, GE et al, (1984, abstract) is cited to show the extension of bacteriophage lambda host range through selection, cloning and characterization of a constitutive lambda receptor gene, wherein the lambda phage was able to infect transformed Salmonella typhimurium and Klebsiella pneumoniae strains of bacteria.

49. Fel'dman, Iu M et al (1975, abstract) is cited to show a polyvalent therapeutic staphylococcal bacteriophage that was able to kill 101 strains of coagulase positive staphylococci out of 147 strains, and 6 coagulase negative strains of staphylococci.

50. Reynaud et al (1992) is cited to show a bacteriophage for E.coli that evidenced a host range for 95 strains of O103 and 7 strains that were of an unknown serogroup (see page 208, Table 1), that was ineffective as a therapeutic agent despite the fact that the bacteriophage was highly virulent (see page 210, paragraph 5, bottom of page).

51. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
May 30, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600